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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Sette *et al.*

Appl. No. 10/031,345

§ 371 Date: July 22, 2002  
(National Phase of PCT/US00/19774;  
Filed: July 19, 2000)

For: **Inducing Cellular Immune  
Responses to Hepatitis C Virus  
Using Peptide and Nucleic Acid  
Compositions**

Confirmation No. 6431

Art Unit: 1644

Examiner: *To be assigned*

Atty. Docket: 2060.0030006/EKS/PAJ/M-M

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**First Supplemental Information Disclosure Statement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450  
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed herewith, in connection with the above-captioned application.

A copy of document AS27 is included. Copies of all other documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/357,737, Sette *et al.*, filed July 19, 1999, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

Sette *et al.*  
Appl. No. 10/031,345

U.S. Patent Application No. 08/205,713, Grey *et al.*, filed March 4, 1994 and was submitted to the United States Patent and Trademark Office in a First Supplemental Information Disclosure Statement in Appl. No. 09/357,737 on March 18, 2004 as document **AS26**;

U.S. Patent Application No. 08/347,610, Kubo *et al.*, filed December 1, 1994 and was submitted to the United States Patent and Trademark Office in a First Supplemental Information Disclosure Statement in Appl. No. 09/357,737 on March 18, 2004 as document **AT26**;

U.S. Patent Application No. 09/017,524, Kubo *et al.*, filed February 3, 1998 and was submitted to the United States Patent and Trademark Office in a First Supplemental Information Disclosure Statement in Appl. No. 09/357,737 on March 18, 2004 as document **AR27**; and

U.S. Patent Application No. 09/357,737, Sette *et al.*, filed July 19, 1999 and submitted herewith as document **AS27**.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior

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art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

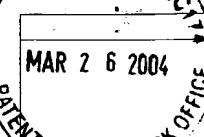
Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Peter A. Jackman  
Attorney for Applicants  
Registration No. 45,986

Date: March 26, 2004  
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MAR 26 2004 FORM PTO-1449 <u>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 2060.0030006/EKS/PAJ/M-M	APPLICATION NO. 10/031,345
		APPLICANT Sette et al.	
		§ 371 DATE: July 22, 2002 (National Phase of PCT/US00/19774; Filed July 19, 2000)	GROUP 1644

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC				RECEIVED		
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	AE1	5,662,907	09/02/1997	Kubo et al.	TECH CENTER 1600/2900		01/25/1994
	AF1	5,932,224	08/03/1999	Chisari			06/06/1995
	AG1	6,037,135	03/14/2000	Kubo et al.			11/29/1993
	AH1	2002/0098197 A1	07/25/2002	Sette et al.			05/30/1995
	AI1	2002/0168374 A1	11/14/2002	Kubo et al.			03/20/1997
	AJ1	2002/0177694 A1	11/28/2002	Sette et al.			02/03/1998
	AK1	2003/0152580 A1	08/14/2003	Sette et al.			11/23/1994

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	WO 01/21189 A1	03/29/2001	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR		
	AS	26	Copy of co-pending U.S. Patent Application No. 08/205,713, Grey et al., filed March 4, 1994 (NOT PUBLISHED)
	AT	26	Copy of co-pending U.S. Patent Application No. 08/347,610, Kubo et al., filed December 1, 1994 (NOT PUBLISHED)

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	AR	<u>27</u>	Copy of co-pending U.S. Patent Application No. 09/017,524, Kubo et al., filed February 3, 1998 (NOT PUBLISHED)
	AS	<u>27</u>	Copy of co-pending U.S. Patent Application No. 09/357,737, Sette et al., filed July 19, 1999 (NOT PUBLISHED)
	AT	<u>27</u>	Battegay, M., et al., "Patients with chronic hepatitis C have circulating cytotoxic T cells which recognize hepatitis C virus-encoded peptides binding to HLA-A2.1 molecules," J. Virol. 69:2462-2470, American Society for Microbiology (1995)

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>28</u>	Bruss, V., "A Short Linear Sequence in the Pre-S Domain of the Large Hepatitis B Virus Envelope Protein Required for Virion Formation," <i>J. Virol.</i> 71:9350-9357, American Society for Microbiology (1997)
AS	<u>28</u>	Chang, K-M., et al., "Identification of HLA-A3 and -B7-Restricted CTL Response to Hepatitis C Virus in Patients with Acute and Chronic Hepatitis C," <i>J. Immunol.</i> 162:1156-1164, The American Association of Immunologists (January 1999)
AT	<u>28</u>	Diepolder, H.M., et al., "Immunodominant CD4 <sup>+</sup> T-Cell Epitope within Nonstructural Protein 3 in Acute Hepatitis C Virus Infection," <i>J. Virol.</i> 71:6011-6019, American Society for Microbiology (1997)

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AR	<u>29</u>	Diepolder, H.M., et al., "The role of hepatitis C virus specific CD4 <sup>+</sup> T lymphocytes in acute and chronic hepatitis C," <i>J. Mol. Med.</i> 74:583-588, Elsevier Scientific Publishing Co. (1996)
AS	<u>29</u>	Lamonaca, V., et al., "Conserved Hepatitis C Virus Sequences Are Highly Immunogenic for CD4 <sup>+</sup> T Cells: Implications for Vaccine Development," <i>Hepatology</i> 30:1088-1098, W.B. Saunders Company (October 1999)
AT	<u>29</u>	Preisler-Adams, S., et al., "Complete nucleotide sequence of a hepatitis B virus subtype adw2, and identification of three types of C open reading frame," <i>Nucleic Acids Res.</i> 21:2258, Oxford University Press (1993)

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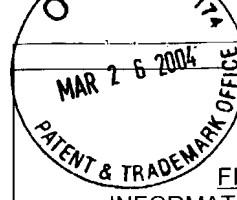
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	AO						Yes No
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>30</u>	Prezzi, C., et al., "Virus-specific CD8 <sup>+</sup> T cells with type 1 or type 2 cytosine profile are related to different disease activity in chronic hepatitis C virus infection," <i>Eur. J. Immunol.</i> 31:894-906, Wiley-VCH Verlag GmbH (March 2001)
AS	<u>30</u>	Rehermann, B., et al., "Cytotoxic T Lymphocyte Responsiveness after Resolution of Chronic Hepatitis GB Virus Infection," <i>J. Clin. Invest.</i> 97:1655-1665, American Society for Clinical Investigation (1996)
AT	<u>30</u>	Rice, C.M., and Walker, C.M., "Hepatitis C virus-specific T lymphocyte responses," <i>Curr. Opin. Immunol.</i> 7:532-538, Current Biology (1995)

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	31	Rothstein, K.D., and Munoz, S.J., "Interferon and other therapies for hepatitis B and hepatitis C infections," <i>Clin. Lab. Med.</i> 16:465-491, W.B. Saunders (1996)
	AS	31	Scognamiglio, P., et al., "Presence of Effector CD8 <sup>+</sup> T Cells in Hepatitis C Virus-Exposed Healthy Seronegative Donors," <i>J. Immunol.</i> 162:6681-6689, The American Association of Immunologists (June 1999)
	AT	31	Shirai, M., et al., "Use of intrinsic and extrinsic helper epitopes for <i>in vivo</i> induction of anti-hepatitis C virus cytotoxic T lymphocytes (CTL) with CTL epitope peptide vaccines," <i>J. Infect. Dis.</i> 173:24-31, University of Chicago Press (1996)

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